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Joseph D. Kuborn
Andrus, Sceales, et al
100 E. Wisconsin Ave.
Ste. 1100
Milwaukee, WI 53202

EXAMINER

SMITH, TERRI L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/682,421

Applicant(s)

BRODNICK, DONALD E.

Examiner

Terri L. Smith

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 February 2006 has been entered.

Response to Arguments

2. Applicant's arguments filed on 28 April 2006 have been fully considered but they are not persuasive.

3. In response to Applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e., in Applicant's REMARKS on page 3, lines 15–page 4, lines 1–5) are not recited as set forth in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The Bornn et al. references cited by the Examiner in the Office Action mailed on 15 March 2006 clearly read on the claimed limitations regarding a reference signal as set forth in the claimed limitation. Applicant's statement that "usually the terms "common" and "reference" are synonymous" (page 3, line 15) and Applicant's statement that "Bornn et al.'s use of the term "reference" is made synonymous with the term "common" (Bornn et al. column 10, line 4 and column 20, line 57)" (page 2, lines 22–24) is an indication that the

Art Unit: 3762

Bornn et al. reference reads on the claimed limitation in the broadest reasonable interpretation, which meets the requirement for claim interpretation during examination.

4. In that there are no allowable base claims, Applicant's arguments regarding all claims are allowable as being dependent upon an allowable base claim are moot.

5. Consequently, Examiner maintains the Office Action mailed on 15 March 2006 and re-submitted herein below in its entirety.

Claim Objections

6. Claims 1–15 are objected to because of the following informalities: In claim 1 on line 5, it appears that the word “of” is missing between the words “one” and “the.” Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1–4, 15–18, 29–33, 44–48, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Bornn et al., U.S. Patent 5,564,429.

9. Regarding claims 1, 16, 30 and 45, Bornn et al. disclose a plurality of electrodes configured on an electrode belt/a belt adapted for attachment to a patient's upper torso (Figs. 1A and 2A), wherein a plurality of electrodes does not include electrodes for attachment to a patient's limbs, and further wherein at least one of a plurality of electrodes is attachable to a patient's back/chest (Figs. 1A and 2A; column 9, lines 20 and 27–30); an acquisition

Art Unit: 3762

module/device coupled to a plurality of electrodes/a belt for acquiring electrical signals from a plurality of electrodes (Figs. 3A–3B and 12A–12B); a signal processor coupled to an acquisition module for generating a plurality of electrocardiogram precordial (it is inherent that precordial means situated or occurring in front of the heart) leads from the acquired signals/electrical signals (Figs. 3A–3B, 12A–12B, and 14A), wherein a signal processor generates a reference signal from an electric signal acquired from at least one of a plurality of electrodes that is attachable to a patient's back (column 10, lines 1–6; column 9, lines 57–67); and a transmitter coupled to an acquisition module for transmitting a plurality of electrocardiogram precordial leads/to a remote location (Figs. 1A, 2A, 3A–3B, 12A–12B, and 14A; column 10, lines 37–41; column 4, lines 3–6) and a receiver wirelessly coupled to a transmitter for receiving an acquired electrical signals (Figs. 1A, 2A, 3A–3B, 12A–12B, and 14A; column 4, lines 3–6).

10. Bornn et al. disclose a belt adapted to be attached around the circumference of a patient's upper torso, and wherein a plurality of electrodes are coupled to a belt so that when a belt is attached to a patient each one of a plurality of electrodes is generally positioned in a plane perpendicular to a longitudinal axis approximately defined by a patient's spine (claims 2, 17, 31, and 46) (Figs. 1A and 2A); a belt is adapted to be attached around the circumference of a patient's upper torso at a level slightly below a patient's breast (claims 3, 18, 32, and 47) (Figs. 1A and 2A); a transmitter coupled to an acquisition module and a receiver coupled to an electrocardiogram machine (Figs. 1A and 2A), wherein a transmitter, an acquisition module, and a signal processor for generating a plurality of electrocardiogram precordial leads from the acquired electrical signals are coupled to a belt (Figs. 1A and 2A), wherein a receiver is coupled to an electrocardiogram machine (Figs. 1A and 2A; column 13, line 52–column 14, lines 1–3),

Art Unit: 3762

and wherein a plurality of electrocardiogram precordial leads are wirelessly transmitted from a transmitter to a receiver to a remote location (claims 4, 33, and 48) (Figs. 1A, 2A, 3A-3B, 12A-12B, and 14A; column 4, lines 3-6; column 13, line 52-column 14, lines 1-3); an electrocardiogram machine wirelessly coupled to an acquisition module and a telemetry monitor coupled to an electrocardiogram machine (claims 15, 29, 44, and 59) (Figs. 1A, 2A, 3A-3B, 12A-12B, and 14A; column 4, lines 3-6; column 13, line 52-column 14, lines 1-3).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 5-6, 19-20, 34-35, and 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornn et al., U.S. Patent 5,564,429 as applied to claims 1, 16, 30, and 45 above, and in view of Segalowitz, U.S. Patent 5,511,533.

13. Bornn et al. do not disclose a signal processor generates a plurality of electrocardiogram precordial leads from the acquired electrical signals by generating an approximation of an electrical potential near the center of a patient's heart based on the acquired electrical signals (claims 5, 19, 34, and 49) and is an approximation of Wilson's central terminal (claims 6, 20, 35, and 50) and. However, Segalowitz discloses a signal processor generates a plurality of electrocardiogram precordial leads from the acquired electrical signals (column 27, lines 49-56, 64-66; column 28, line 1; column 35, lines 34-52) by generating an approximation of an electrical potential near the center of a patient's heart based on the acquired electrical signals

Art Unit: 3762

(Fig. 17, element 321 with details of element 321 shown in Fig. 18; column 30, lines 57–58 and 60–62; column 31, lines 4–9 and 24–38) and an approximation of an electrical potential near the center of a patient's heart is an approximation of Wilson's central terminal (column 30, lines 57–62) [In view of a teaching on Wilson's terminal, Segalowitz teaches that the central terminal is the zero or reference point generally referred to as the central terminal (column 17, lines 63–67; column 18, lines 1–2)] to provide a “smart” method of electrocardiographic data analysis and processing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Bornn et al. to include a signal processor generates a plurality of electrocardiogram precordial leads from the acquired electrical signals by generating an approximation of an electrical potential near the center of a patient's heart based on the acquired electrical signals and an approximation of an electrical potential near the center of a patient's heart is an approximation of Wilson's central terminal, as taught by Segalowitz to provide a “smart” method of electrocardiographic data analysis and processing.

14. Claims 7, 14, 21, 28, 36, 43, 51, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornn and Segalowitz as applied to claims 1, 5, 16, 19, 30, 34, 45, and 49 above, and further in view of Shusterman et al., U.S. Patent 6,389,308.

15. Bornn et al. nor Segalowitz discloses a signal processor generates an approximation of an electrical potential near the center of a patient's heart by determining a weighted combination of a plurality of the acquired electrical signals (claims 7, 21, 36, and 51) and an acquisition module is capable of storing precordial leads for approximately one month (claims 14, 28, 43, and 58). However, Shusterman et al. disclose a signal processor generates an approximation of an electrical potential near the center of a patient's heart by determining a weighted combination of

Art Unit: 3762

a plurality of the acquired electrical signals (column 7, lines 48–50) to achieve the optimal sensitivity in the detection of hidden or small ECG changes (column 7, lines 40–41) and an acquisition module (Fig. 1) is capable of storing precordial leads for approximately one month (Fig. 13; column 5, lines 66–67) for focusing on a patient's critical primary elements (column 5, lines 16–17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Bornn et al. and Segalowitz to include a signal processor to generate an approximation of an electrical potential near the center of a patient's heart by determining a weighted combination of a plurality of the acquired electrical signals and an acquisition module is capable of storing precordial leads for approximately one month, as taught by Shusterman et al., to achieve the optimal sensitivity in the detection of hidden or small ECG changes and for focusing on a patient's critical primary elements.

16. Claims 8, 11–12, 22, 25–26, 37, 40–41, 52, and 55–56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornn et al. and Segalowitz as applied to claims 1, 16, 30, and 45 above, and further in view of GE Medical Systems Information Technologies, *ACI-TIPT Standard 12/15 – Lead Placement*.

17. Bornn et al. nor Segalowitz discloses a plurality of electrodes includes a first electrode attachable to a patient's chest in approximately the fourth intercostal space at the right border of the sternum, a second electrode attachable to a patient's chest in approximately the fifth intercostal space at the anterior axillary line, a third electrode attachable to a patient's back in approximately the fifth intercostal space under the left mid-scapular line, and a fourth electrode attachable to a patient's back in approximately the fifth intercostal space under the right mid-

Art Unit: 3762

scapular line (claims 8, 22, 37, and 52) and a plurality of electrodes includes a first electrode capable of being attachable to a patient's back in approximately the fifth intercostal space under the right mid-scapular line and at least one electrode attachable to a patient's chest (claims 11, 25, 40, and 55). However, the article by GE Medical Systems Information Technologies, *ACI-TIPT Standard 12/15 – Lead Placement*, teaches that a plurality of electrodes includes a first electrode attachable to a patient's chest in approximately the fourth intercostal space at the right border of the sternum, a second electrode attachable to a patient's chest in approximately the fifth intercostal space at the anterior axillary line, a third electrode attachable to a patient's back in approximately the fifth intercostal space under the left mid-scapular line, and a fourth electrode attachable to a patient's back in approximately the fifth intercostal space under the right mid-scapular line (Figures on first and second pages) and a plurality of electrodes includes a first electrode capable of being attachable to a patient's back in approximately the fifth intercostal space under the right mid-scapular line (first page) and at least one electrode attachable to a patient's chest (second page) to provide guidelines for ECG placement to correctly determine ECG lead placement (first page). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Bornn et al. and Segalowitz to include a plurality of electrodes includes a first electrode attachable to a patient's chest in approximately the fourth intercostal space at the right border of the sternum, a second electrode attachable to a patient's chest in approximately the fifth intercostal space at the anterior axillary line, a third electrode attachable to a patient's back in approximately the fifth intercostal space under the left mid-scapular line, and a fourth electrode attachable to a patient's back in approximately the fifth intercostal space under the

Art Unit: 3762

right mid-scapular line and a plurality of electrodes includes a first electrode capable of being attachable to a patient's back in approximately the fifth intercostal space under the right mid-scapular line and at least one electrode attachable to a patient's chest, as taught by GE Medical Systems Information Technologies, to provide guidelines for ECG lead placement to correctly determine ECG lead placement.

18. Bornn et al. and GE Medical Systems Information Technologies do not disclose a signal processor uses a signal acquired from a first electrode as an approximation of an electrical potential near the center of the patient's heart (claims 12, 26, 41, and 56). However, Segalowitz discloses a signal processor uses a signal acquired from a first electrode (Fig. 18, element 363 on strip 321) as an approximation of an electrical potential near the center of the patient's heart (Fig. 17, element 321 with details of element 321 shown in Fig. 18; column 30, lines 57–58 and 60–62; column 31, lines 4–9 and 24–38) to provide a “smart” method of electrocardiographic data analysis and processing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified invention of Bornn et al. and GE Medical Systems Information Technologies to include a signal processor uses a signal acquired from a first electrode as an approximation of an electrical potential near the center of the patient's heart, as taught by Segalowitz to provide a “smart” method of electrocardiographic data analysis and processing.

19. Claims 9, 23, 38, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornn et al., Segalowitz, and GE Medical Systems Information Technologies as applied to claims 8, 22, 37, and 52 above, and further in view of, Shusterman et al., U.S. Patent 6,389,308.

Art Unit: 3762

20. Bornn et al. nor Segalowitz nor GE Medical Systems Information Technologies discloses a signal processor generates an approximation of an electrical potential near the center of a patient's heart by determining a weighted combination of the signals acquired from a plurality of electrodes. However, Shusterman et al. disclose a signal processor generates an approximation of an electrical potential near the center of a patient's heart by determining a weighted combination of the signals acquired from a plurality of electrodes (column 7, lines 48–50) to achieve the optimal sensitivity in the detection of hidden or small ECG changes (column 7, lines 40–41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Bornn et al., Segalowitz, and GE Medical Systems Information Technologies to include a signal processor to generate an approximation of an electrical potential near the center of a patient's heart by determining a weighted combination of the signals acquired from a plurality of electrodes, as taught by Shusterman et al., to achieve the optimal sensitivity in the detection of hidden or small ECG changes.

21. Claims 10, 24, 39, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornn et al., Segalowitz, GE Medical Systems Information Technologies, and Shusterman et al. as applied to claims 9, 23, 38, and 53 above, and further in view of Pritchard, U.S. Patent 5,615,687.

22. Bornn et al. nor Segalowitz nor GE Medical Systems Information Technologies nor Shusterman et al. discloses a signal processor generates each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of a patient's heart from each one of the signals acquired from a first electrode and a second electrode. However, Pritchard discloses a signal processor generates each one of a

Art Unit: 3762

plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of a patient's heart from each one of the signals acquired from a first electrode and a second electrode (column 1, lines 59–62) to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician (column 1, lines 44–46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Bornn et al., Segalowitz, GE Medical Systems Information Technologies, and Shusterman et al. to include a signal processor to generate each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of a patient's heart from each one of the signals acquired from a first electrode and a second electrode, as taught by Pritchard, to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician.

23. Claims 13, 27, 42, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornn et al., Segalowitz, and GE Medical Systems Information Technologies as applied to claims 12, 26, 41, and 56 above, and further in view of, Pritchard, U.S. Patent 5,615,687.

24. Bornn et al. nor Segalowitz nor GE Medical Systems Information Technologies discloses a signal processor generates each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of a patient's heart from each one of the signals acquired from the at least one electrode on a patient's chest. However, Pritchard discloses a signal processor generates each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of a

Art Unit: 3762

patient's heart from each one of the signals acquired from the at least one electrode on a patient's chest (column 1, lines 59–62) to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician (column 1, lines 44–46).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Bornn et al., Segalowitz, and GE Medical Systems Information Technologies to include a signal processor to generate each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of a patient's heart from each one of the signals acquired from the at least one electrode on a patient's chest, as taught by Pritchard, to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician.

25. Claims 60–64 and 71–72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornn et al., U.S. Patent 5,564,429 and in view of Segalowitz, U.S. Patent 5,511,553 and Shusterman et al., U.S. Patent 6,389,308.

26. Regarding Claim 60, Bornn et al. disclose positioning a plurality of electrodes on a patient's upper torso, a plurality of electrodes including at least one electrode positionable on a patient's chest and at least one electrode positionable on a patient's back (Figs. 1A and 2A; column 9, lines 20 and 27–30), a plurality of electrodes does not include electrodes for positioning on a patient's limbs, acquiring electrical signals from a plurality of electrodes with an acquisition module (Figs. 3A–3B and 12A–12B) processing an electrical signal acquired from at least one electrode positioned on a patient's back as a reference signal (column 10, lines 1–6;

Art Unit: 3762

column 9, lines 57–67). Bornn et al. do not disclose generating an approximation of an electrical potential near the center of a patient's heart by determining a weighted combination of a plurality of the acquired electrical signals and generating a plurality of electrocardiogram precordial leads from the acquired electrical signals by subtracting an approximation of an electrical potential near the center of a patient's heart from each one of the signals acquired from at least one electrode on a patient's chest.

27. Nonetheless, Segalowitz discloses acquiring electrical signals from a plurality of electrodes (column 27, lines 49–56, 64–66; column 28, line 1; column 35, lines 34–52) with an acquisition module to transmit a single encoded radio frequency signal which carries the twelve-lead electrocardiographic multiple heart signals (column 27, lines 65–67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Bornn et al. to include acquiring electrical signals from a plurality of electrodes with an acquisition module, as taught by Segalowitz, to transmit a single encoded radio frequency signal which carries the twelve-lead electrocardiographic multiple heart signals.

28. Shusterman et al. disclose generating an approximation of an electrical potential near the center of a patient's heart by determining a weighted combination of a plurality of the acquired electrical signals; and generating a plurality of electrocardiogram precordial leads from the acquired electrical signals by subtracting an approximation of the electrical potential near the center of a patient's heart from each one of the signals acquired from the at least one electrode on a patient's chest (column 7, lines 48–50) to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician (column 1, lines 44–46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

Art Unit: 3762

invention was made to have modified the invention of Bornn et al. to generate a plurality of electrocardiogram precordial leads from the acquired electrical signals by subtracting an approximation of the electrical potential near the center of a patient's heart from each one of the signals acquired from the at least one electrode on a patient's chest, as taught by Shusterman et al., to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician.

29. Bornn et al. disclose a belt adapted to be attached around the circumference of a patient's upper torso, and wherein a plurality of electrodes are coupled to a belt so that when a belt is attached to a patient each one of a plurality of electrodes is generally positioned in a plane perpendicular to a longitudinal axis approximately defined by a patient's spine (claim 61) (Figs. 1A and 2A); a belt is adapted to be attached around the circumference of a patient's upper torso at a level slightly below a patient's breast (claim 62) (Figs. 1A and 2A); a an act of wirelessly transmitting a plurality of electrocardiogram precordial leads form a transmitter coupled to a belt to a receiver (claim 63) (Figs. 1A, 2A, 3A-3B, 12A-12B, and 14A; column 4, lines 3-6; column 13, line 52-column 14, lines 1-3); an act of wirelessly coupling a telemetry monitor to a plurality of electrodes (claim 72) (Figs. 1A, 2A, 3A-3B, 12A-12B, and 14A; column 4, lines 3-6).

30. Bornn et al. do not disclose generating an approximation of an electrical potential near the center of a patient's heart based on the acquired electrical signals includes the act of generating an approximation of Wilson's central terminal (claim 64). However, Segalowitz discloses generating an approximation of an electrical potential near the center of a patient's heart based on the acquired electrical signals (Fig. 17, element 321 with details of element 321 shown in Fig. 18; column 30, lines 57-58 and 60-62; column 31, lines 4-9 and 24-38) includes

Art Unit: 3762

the act of generating an approximation of Wilson's central terminal a signal processor generates a plurality of electrocardiogram precordial leads from the acquired electrical signals (column 30, lines 57–62). [In view of a teaching on Wilson's terminal, Segalowitz teaches that the central terminal is the zero or reference point generally referred to as the central terminal (column 17, lines 63–67; column 18, lines 1–2)] to provide a “smart” method of electrocardiographic data analysis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Bornn et al. to include generating an approximation of an electrical potential near the center of a patient's heart based on the acquired electrical signals includes the act of generating an approximation of Wilson's central terminal, as taught by Segalowitz to provide a “smart” method of electrocardiographic data analysis and processing.

31. Bornn et al. do not disclose the act of acquiring electrical signals from a plurality of electrodes includes the act of acquiring electrical signals for approximately one month (claim 71). However, Shusterman et al. disclose an act of acquiring electrical signals from a plurality of electrodes (Fig. 1) includes an act of acquiring electrical signals for approximately one month (Fig. 13; column 5, lines 66–67) for focusing on a patient's critical primary elements (column 5, lines 16–17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Bornn et al. to include an act of acquiring electrical signals from a plurality of electrodes includes an act of acquiring electrical signals for approximately one month, as taught by Shusterman et al. for focusing on a patient's critical primary elements.

Art Unit: 3762

32. Claims 65–66 and 68–69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bornn et al., Segalowitz, and Shusterman et al. as applied to claim 60 above, and further in view of GE Medical Systems Information Technologies, *ACI-TIPT Standard 12/15 – Lead Placement*.

33. Bornn et al. nor Segalowitz nor Shusterman et al. discloses a plurality of electrodes includes a first electrode attachable to a patient's chest in approximately the fourth intercostal space at the right border of the sternum, a second electrode attachable to a patient's chest in approximately the fifth intercostal space at the anterior axillary line, a third electrode attachable to a patient's back in approximately the fifth intercostal space under the left mid-scapular line, and a fourth electrode attachable to a patient's back in approximately the fifth intercostal space under the right mid-scapular line (claim 65). However, the article by GE Medical Systems Information Technologies, *ACI-TIPT Standard 12/15 – Lead Placement*, teaches that a plurality of electrodes includes a first electrode attachable to a patient's chest in approximately the fourth intercostal space at the right border of the sternum, a second electrode attachable to a patient's chest in approximately the fifth intercostal space at the anterior axillary line, a third electrode attachable to a patient's back in approximately the fifth intercostal space under the left mid-scapular line, and a fourth electrode attachable to a patient's back in approximately the fifth intercostal space under the right mid-scapular line (Figures on first and second pages) to provide guidelines for ECG placement to correctly determine ECG lead placement (first page).

34. Bornn et al. nor Segalowitz nor Shusterman et al. discloses a plurality of electrodes includes a first electrode capable of being attachable to a patient's back in approximately the fifth intercostal space under the right mid-scapular line and at least one electrode attachable to a patient's chest (claim 68). However, the article by GE Medical Systems Information

Art Unit: 3762

Technologies, *ACI-TIPT Standard 12/15 – Lead Placement* discloses a plurality of electrodes includes a first electrode capable of being attachable to a patient's back in approximately the fifth intercostal space under the right mid-scapular line (first page) and at least one electrode attachable to a patient's chest (second page) to provide guidelines for ECG placement to correctly determine ECG lead placement (first page). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Bornn et al., Segalowitz and Shusterman et al. to include a plurality of electrodes includes a first electrode attachable to a patient's chest in approximately the fourth intercostal space at the right border of the sternum, a second electrode attachable to a patient's chest in approximately the fifth intercostal space at the anterior axillary line, a third electrode attachable to a patient's back in approximately the fifth intercostal space under the left mid-scapular line, and a fourth electrode attachable to a patient's back in approximately the fifth intercostal space under the right mid-scapular line and a plurality of electrodes that includes a first electrode attachable to a patient's chest in approximately the fourth intercostal space at the right border of the sternum, a second electrode attachable to a patient's chest in approximately the fifth intercostal space at the anterior axillary line, as taught by GE Medical Systems Information Technologies, to provide guidelines for ECG lead placement to correctly determine ECG lead placement.

35. Bornn et al. do not disclose an act of generating an approximation of an electrical potential near the center of a patient's heart includes an act of determining a weighted combination of the signals acquired from a plurality of electrodes (claim 66). However, Shusterman et al. disclose act of generating an approximation of an electrical potential near the

Art Unit: 3762

center of a patient's heart includes an act of determining a weighted combination of the signals acquired from a plurality of electrodes (column 7, lines 48–50) to achieve the optimal sensitivity in the detection of hidden or small ECG changes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Bornn et al. to include an act of generating an approximation of an electrical potential near the center of a patient's heart includes an act of determining a weighted combination of the signals acquired from a plurality of electrodes, as taught by Shusterman et al. to achieve the optimal sensitivity in the detection of hidden or small ECG changes.

36. Bornn et al. do not disclose an act of generating an approximation of an electrical potential near the center of a patient's heart includes an act of using a signal acquired from a first electrode as an approximation of the electrical potential near the center of a patient's heart (claim 69): However, Segalowitz discloses an act of generating an approximation of an electrical potential near the center of a patient's heart includes an act of using a signal acquired from a first electrode (Fig. 18, element 363 on strip 321) as an approximation of the electrical potential near the center of a patient's heart (Fig. 17, element 321; column 31, lines 8–9 and 28–30) to provide a “smart” method of electrocardiographic data analysis and processing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Bornn et al. to include an act of generating an approximation of an electrical potential near the center of a patient's heart includes an act of using a signal acquired from a first electrode as an approximation of the electrical potential near the center of a patient's heart, as taught by Segalowitz to provide a “smart” method of electrocardiographic data analysis and processing.

Art Unit: 3762

37. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bornn et al., Segalowitz, Shusterman et al., and GE Medical Systems Information Technologies as applied to claim 66 above, and further in view of Pritchard, U.S. Patent 5,615,687.

38. Bornn et al. nor Segalowitz nor Shusterman et al. nor GE Medical Systems Information Technologies discloses a signal processor generates each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of a patient's heart from each one of the signals acquired from a first electrode and a second electrode. However, Pritchard discloses a signal processor generates each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of a patient's heart from each one of the signals acquired from a first electrode and a second electrode (column 1, lines 59–62) to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Bornn et al., Segalowitz, Shusterman et al., and GE Medical Systems Information Technologies to include a signal processor to generate each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of a patient's heart from each one of the signals acquired from a first electrode and a second electrode, as taught by Pritchard, to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician.

Art Unit: 3762

39. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bornn et al., Segalowitz, and Shusterman et al., as applied to claim 69 above, and further in view of Pritchard, U.S. Patent 5,615,687.

40. Bornn et al. nor Segalowitz nor Shusterman et al. discloses a signal processor generates each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of a patient's heart from each one of the signals acquired from the at least one electrode on a patient's chest. However, Pritchard discloses a signal processor generates each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of a patient's heart from each one of the signals acquired from the at least one electrode on a patient's chest (column 1, lines 59–62) to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician (column 1, lines 44–46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Bornn et al., Segalowitz, and Shusterman et al. to include a signal processor to generate each one of a plurality of electrocardiogram precordial leads by subtracting an approximation of an electrical potential near the center of a patient's heart from each one of the signals acquired from the at least one electrode on a patient's chest, as taught by Pritchard, to convert the raw electrical signals into meaningful information that can be displayed or printed out for review by a physician.

Conclusion

41. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3762

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

42. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



TLS

September 29, 2006

29 September 2006



GEORGE R. EVANISKO
PRIMARY EXAMINER

10/1/06